

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF PUERTO RICO

UNITED STATES OF AMERICA,

Plaintiff,

v.

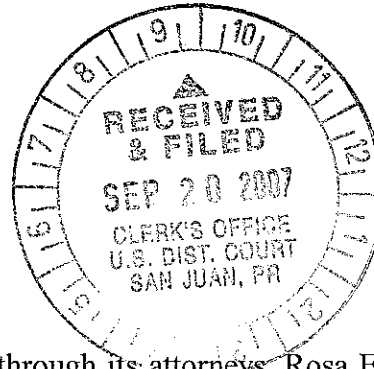
FELIX COTTO-ORTIZ,

Defendant.

Criminal No.07-075(CCC)

PLEA AGREEMENT

TO THE HONORABLE COURT:



COMES NOW the United States of America, by and through its attorneys, Rosa Emilia Rodríguez-Vélez, United States Attorney for the District of Puerto Rico, José A. Ruiz-Santiago, Assistant U.S. Attorney, Chief, Criminal Division, and Julia Díaz-Rex, Assistant United States Attorney, for said District and the defendant, **FELIX COTTO-ORTIZ**, and the defendant's counsel, Armando González, Esq., pursuant to Rule 11(c)(1)(A) and (B) of the Federal Rules of Criminal Procedure, and state to this Honorable Court, that they have reached an agreement, the terms and conditions of which are as follows:

1. **COUNT TO WHICH DEFENDANT PLEADS GUILTY**

The defendant agrees to plead guilty to COUNT ONE of the Indictment pending against him, charging him engaging in a conspiracy to defraud the United States, in violation of Title 18, United States Code, Section 371.

2. **MAXIMUM PENALTIES**


The maximum penalty for the offense charged in COUNT ONE of the indictment is a term of imprisonment of not more than five (5) years and/or a fine of not more than \$500,000, plus a term

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of supervised release of not more than three (3) years in addition to any term of incarceration, and a special assessment of one hundred dollars (\$100.00) per count, as required by Title 18, United States Code, Section 3013(a).

3. FINES AND/OR RESTITUTION

The Court may, pursuant to Section 5E1.2(I) of the Sentencing Guidelines, Policy Statements, Application, and Background Notes, order the defendant to pay a fine sufficient to reimburse the government for the costs of any imprisonment and/or supervised release ordered and also the Court may impose restitution. The defendant agrees to execute a financial statement to the United States (OBD Form 500). The United States will make no recommendations as to the imposition of fines.



4. RULE 11(c)(1)(B) WARNINGS



The defendant is aware that the defendant's sentence is within the sound discretion of the sentencing judge, but the same may be imposed following the United States Sentencing Guidelines, Policy Statements, Application, and Background Notes as advisory to the imposition of sentence. The defendant is aware that the Court has jurisdiction and authority to impose any sentence within the statutory maximum set for the offense to which the defendant pleads guilty. If the Court should impose a sentence up to the maximum established by statute, the defendant cannot, for that reason alone, withdraw a guilty plea, and will remain bound to fulfill all of the obligations under this plea agreement.


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5. ADVISORY NATURE OF THE SENTENCING GUIDELINES

The defendant is aware that pursuant to the decisions issued on January 12, 2005, by the Supreme Court of the United States in the cases of United States v. Booker and United States v. Fanfan, 125 S.Ct. 738, 2005 WL 50108 (January 12, 2005), the Sentencing Guidelines are no longer mandatory and must be considered effectively advisory.

6. SENTENCING GUIDELINE CALCULATIONS

The United States and the defendant agree that the following Sentencing Guidelines calculations apply to the defendant's conduct with regard to COUNT ONE of the indictment:



SCENARIO 2: PLEA AGREEMENT (COUNT ONE)		Levels
BASE OFFENSE LEVEL [USSG § 2N2.1 and § 2B1.1]		6
Specific Offense Characteristics	Defendant to be held accountable for a loss of more than \$70,000 but less than \$120,000 [§ 2B1.1(b)(1)(D)]	+8
	The offense involved 10 or more or was committed through mass-marketing. [§ 2B1.1(b)(2)(A)]	+2
Role in Offense	None.	+0
Acceptance of Responsibility [USSG § 3E1.1]		-3
TOTAL OFFENSE LEVEL		13
TOTAL Imprisonment Range @ Criminal History Category 'I'		12-18

7. SPECIFIC SENTENCE RECOMMENDATION

The parties agree to recommend that the defendant be sentenced to the lower end of the applicable guideline, that is, 12 months and one day under Criminal History Category 'I'. This recommendation is subject to defendant possessing a Criminal History Category (CHC) of 'I'. Should

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the defendant possess a CHC greater than 'I', the parties agree to recommend a sentence of imprisonment at the lower end of the applicable guideline.

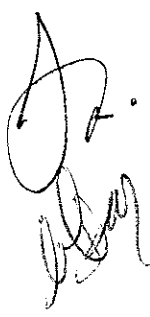
8. NO FURTHER ADJUSTMENTS OR DEPARTURES

The United States and the defendant agree that no further adjustments or departures to the defendant's total offense level shall be sought by the parties.

9. NO STIPULATION AS TO CRIMINAL HISTORY CATEGORY

The parties do not stipulate any assessment as to the defendant's Criminal History Category.

10. UNITED STATES' RESERVATION OF RIGHTS



The United States reserves the right to carry out its responsibilities under guidelines sentencing. Specifically, the United States reserves the right: (a) to bring its version of the facts of this case including its file and any investigative files to the attention of the probation office in connection with that office's preparation of a presentence report; (b) to dispute sentencing factors or facts material to sentencing; and, (c) to seek resolution of such factors or facts in conference with opposing counsel and the probation office.

11. SATISFACTION WITH COUNSEL

The defendant represents to the Court to be satisfied with counsel, Armando González, Esq., and indicates that counsel has rendered effective legal assistance.

12. RIGHTS SURRENDERED BY DEFENDANT THROUGH GUILTY PLEA

Defendant understands that by entering into this agreement, defendant surrenders certain rights as provided in this agreement. Defendant understands that the right of criminal defendants include the following:

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a. If the defendant had persisted in a plea of not guilty to the charges, defendant would have the right to a speedy jury trial with the assistance of counsel. The trial may be conducted by a judge sitting without a jury if the defendant, the United States and the judge agree.

b. If a jury trial is conducted, the jury would be composed of twelve lay persons selected at random. The defendant and defendant's attorney would assist in selecting the jurors by removing prospective jurors for cause where actual bias or other disqualification is shown, or by removing prospective jurors without cause by exercising peremptory challenges. The jury would have to agree, unanimously, before it could return a verdict of either guilty or not guilty. The jury would be instructed that the defendant is presumed innocent, that it could not convict the defendant unless, after hearing all the evidence, it was persuaded of the defendant's guilt beyond a reasonable doubt, and that it was to consider each charge separately.

c. If a trial is held by the judge without a jury, the judge would find the facts and, after hearing all the evidence and considering each count separately, determine whether or not the evidence established the defendant's guilt beyond a reasonable doubt.

d. At a trial, the United States would be required to present its witnesses and other evidence against the defendant. The defendant would be able to confront those witnesses and defendant's attorney would be able to cross-examine them. In turn, the defendant could present witnesses and other evidence in defendant's own behalf. If the witnesses for the defendant would not appear voluntarily, defendant could require their attendance through the subpoena power of the Court.


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e. At a trial, the defendant could rely on the privilege against self-incrimination to decline to testify, and no inference of guilty could be drawn from his refusal to testify. If the defendant desired to do so, the defendant could testify in his own behalf.

13. STATEMENT OF FACTS

The accompanying Statement of Facts signed by the defendant is hereby incorporated into this plea agreement. Defendant adopts the Statement of Facts and agrees that the facts therein are accurate in every respect and, had the matter proceeded to trial, that the United States would have proven those facts beyond a reasonable doubt.

14. LIMITATIONS OF PLEA AGREEMENT



This plea agreement binds only the United States Attorney's Office for the District of Puerto Rico and the defendant; it does not bind any other federal district, state or local authorities. Furthermore, the defendant is fully aware that the Court is not bound by this plea agreement, including but not limited as to: advisory sentencing guidelines calculations, stipulations, and/or sentence recommendations.

15. ENTIRETY OF PLEA AGREEMENT

This written agreement constitutes the complete plea agreement between the United States, the defendant, and the defendant's counsel. The United States has made no promises or representations except as set forth in writing in this plea agreement and deny the existence of any other term and conditions not stated herein.

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16. AMENDMENTS TO PLEA AGREEMENT

No other promises, terms or conditions will be entered unless in writing and signed by all parties.

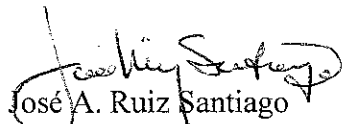
17. WAIVER OF APPEAL

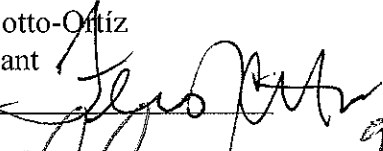
The defendant hereby agrees that if this Honorable Court accepts this Plea Agreement and sentences him/her according to its terms, conditions, and recommendations, the defendant waives and surrenders his right to appeal the judgment and sentence in this case.


18. VOLUNTARINESS OF GUILTY PLEA

The defendant acknowledges that no threats have been made against the defendant and that the defendant is pleading guilty freely and voluntarily because the defendant is guilty.

ROSA EMILIA RODRIGUEZ-VELEZ
United States Attorney


José A. Ruiz Santiago
Assistant U.S. Attorney
Chief, Criminal Division
Dated: 9/20/07

Félix Cotto-Ortiz
Defendant
Dated:  9/20/2007


Armando González
Counsel for Defendant
Dated: 9/20/2007

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I have consulted with my counsel and fully understand all my rights with respect to the Indictment pending against me. Further, I have consulted with my attorney and fully understand my rights with respect to the provision of the Sentencing Guidelines, Policy Statements, Application, and Background Notes which may apply in my case. I have read this plea agreement and carefully reviewed every part of it with my attorneys. I fully understand this agreement and I voluntarily agree to it.

Date:

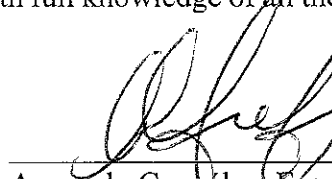
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Félix Cotto-Ortiz
Defendant

I am the attorney for the defendant. I have fully explained to the defendant his rights with respect to the pending Indictment. Further, I have reviewed the provisions of the Sentencing Guidelines, Policy Statements, Application, and Background Notes, and have fully explained to the defendant the provisions of those guidelines which may apply in this case. I have also explained to the defendant the advisory nature of the Sentencing Guidelines. I have carefully reviewed every part this plea agreement with the defendant. To my knowledge, the defendant is entering into this agreement is voluntarily, intelligently and with full knowledge of all the consequences of his plea of guilty.

Date:

9/20/2007


Armando González, Esq.
Counsel for Defendant

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GOVERNMENT'S VERSION OF THE FACTS

In conjunction with the submission of the accompanying plea agreement in this case, the United States of America submits the following statement setting forth the United States' version of the facts leading to the defendant's acceptance of criminal responsibility for Count One of the indictment.

Pharma Blood was a business that advertised, marketed and distributed a cancer treatment for cancer patients by way of the "Pharma Blood Cancer Vaccination" (PCV), an autologous hemoderivative cancer immunotherapy. PCV was a drug that was not approved for use in humans in the United States by the FDA. From mid-June 2003 to June 24, 2004, the PCV was made available to the general public at Pharma Blood Cancer Center, as San Juan Bautista Hospital, in Caguas, Puerto Rico.

Pharma Blood, Inc. was a profit corporation organized under the laws of the State of Florida on April 23, 2002, and duly authorized to do business in Puerto Rico since January 28, 2004. Pharma Blood Medical Center, Inc. was a profit corporation organized under the laws of the Commonwealth of Puerto Rico on or about March 21, 2003. Pharmablood Medical Center, Inc. possessed bank accounts at Banco Bilbao Viscaya and Doral Bank, both financial institutions whose deposits were insured by the Federal Deposit Insurance Corporation. Pharma Blood Research Corporation was a non-profit corporation organized under the laws of the Commonwealth of Puerto Rico on August 18, 2003.

From on or about March 2003 and continuing through to on or about June 24, 2004, in the District of Puerto Rico and elsewhere, and within the jurisdiction of this Court, defendant [1] FELIX COTTO-ORTIZ knowingly and willfully agreed with others to unlawfully market and distribute in interstate commerce the PCV, a drug that was not approved for use in human beings in the United States by the federal Food and Drug Administration, for personal gain and profit, for the purpose of impairing, obstructing and defeating the lawful function of said agency of the United States.



During the time of the conspiracy defendant [1] FELIX COTTO-ORTIZ failed to exercise due diligence in informing himself of the legal requirements to marketing, advertising and distributing the PCV in the United States.

Defendant [1] FELIX COTTO-ORTIZ was a physician not licensed to practice medicine in Puerto Rico, and was President and Executive Director of Pharma Blood Medical Research Center, Inc. Defendant signed advertisement contracts with newspapers (*El Nuevo Día*) for Pharma Blood advertising in Puerto Rico. Defendant also signed a Lease Agreement with Hospital San Juan Bautista, in which office space at said hospital was rented to Pharma Blood.

On July 1, 2003, co-defendant Eduardo Lasalvia-Prisco was issued a special license to practice medicine in Puerto Rico, which allowed him to practice medicine, from July 1, 2003 to June 30, 2004, in the facilities of the San Juan Bautista Hospital, under the immediate supervision of the hospital's medical director.

On October 13, 2003, defendants COTTO, OTERO and CUCCHI appeared in a Channel 2 television news broadcast describing Pharma Blood's Cancer Vaccination.

On September 19, 2003, and on October 14, 2003, the defendant wrote a letters to an FDA official in San Juan, Puerto Rico, requesting an opinion by said federal agency as to whether the Pharma Blood Cancer Vaccination protocol required FDA approval. On November 14, 2003, José F. Pedrós, FDA San Juan Regulatory Office, informed Héctor Nieves, controller for Pharma Blood, that to obtain an official response

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from the FDA as to whether the Pharma Blood was exempt from FDA regulation, Pharma Blood would have to contact the FDA's offices in Rockville, Maryland.

Contact with FDA's Center for Biologics Research (CBER) as to said exemption was not undertaken by persons associated to Pharma Blood, until March 2004, when an Investigational New Drug Application (INDA) was submitted by defendant ALBERTINI on behalf of Pharmablood, Inc. In the same submission to FDA, ALBERTINI requested from FDA-CBER a statement of whether the PCV was exempted from FDA regulation. Said INDA was placed on clinical hold by the FDA in April 2004, for lack of sufficient information provided by Pharma Blood as to the proposed studies. In addition, the FDA informed ALBERTINI that the PCV was not exempt from FDA regulation.

However, since mid-June, 2003, up to before the submission of the INDA, Pharma Blood continued to advertise, market and distribute the PCV in Puerto Rico and outside of Puerto Rico, without authorization from the FDA to do so.

Since it commenced operations in Puerto Rico, up to on or about November 19, 2003, Pharma Blood Medical Center, Inc. collected fees from patients and consultation fees in relation to Pharma Blood's Cancer Vaccination, totaling approximately \$246,841.02, while incurring in advertising expenses totaling approximately \$58,701.94. However, Defendant COTTO, as payment, only received a salary from Pharma Blood of \$500 weekly.

On or about November 20, 2003, defendant ALBERTINI faxed a letter from Pharma Blood's offices in North Miami, to defendant COTTO in Puerto Rico, where ALBERTINI warned COTTO that FDA regulations prohibited the dissemination of information to the public about treatments and drugs not approved by FDA. COTTO claims that he never saw or read this fax letter. However, FDA agents seized this letter from the premises of Pharma Blood's Cancer Center in Hospital San Juan Bautista during the execution of a federal search warrant there on December 2, 2003.

Among the evidence seized during the execution of the federal search warrant was a photocopy of an internet article written by a Cuban physician, that was downloaded on October 23, 2003, titled "Therapeutic vaccines in cancer: current clinical essays." This article was in relation to therapeutic vaccines in cancer. The article stated that "[a]t this moment the regulatory agency in the United States, the Food and Drug Administration (FDA) has not approved any vaccine for use in conventional oncological treatments, however, according to the Physician Data Query database of clinical essays of the National Cancer Institute in the United States, there exist 101 clinical essays of vaccines in use against different tumors, and of these, only 7 are in phase III (4 in melanoma, 2 non-Hodgkin lymphoma and 1 in renal cancer.)"

In addition to this article, the agents seized a one-sheet document titled "Obtaining FDA Approval for an New Biological Product." This article stated that "[b]ecause most biological products also meet the definition of "drugs" under the Federal Food, Drug and Cosmetic Act, they are also subject to regulation by the FDA ... Following initial laboratory and animal testing, a biological product is studied in clinical trials under the Investigational New Drug (IND) application process ... If the data generated from the studies demonstrate that the new product is safe and effective for its intended use, the data are submitted to CBER as part of a Biologics License Application (BLA) for review and, hopefully, final marketing approval."

On or about December 12, 2003, in a meeting with board members of San Juan Bautista Hospital, defendant COTTO denied that defendant LASALVIA had started to work as a physician at Pharma Blood before receiving authorization by the Puerto Rico Medical Examining Board to practice medicine in Puerto Rico. LASALVIA had examined patients and ordered prescription drugs to them during the second half of June 2003, when LASALVIA had no license to practice medicine in Puerto Rico.

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On or about January 30, 2004, defendants COTTO and LASALVIA submitted a research grant application titled "Pharma Blood Research Corporation" to the Department of Health and Human Services' National Institute of Health.

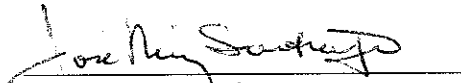
On or about February 19, 2004, defendant COTTO received estimates from Puerto Rico general circulation newspapers *El Nuevo Día* and from *El Vocero*, of costs of placing Pharma Blood advertisements in said newspapers.

On or about February 20, 2004, defendant COTTO signed a Contract/Invoice, number 503, with a publication known as '*Diario Vivir*', for the purpose of advertising Pharma Blood in its March 2004 issue.

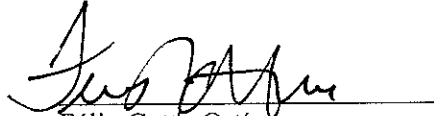
On or about March 30, 2004, defendant COTTO signed an Advertising Contract with a weekly publication known as '*Todo*', for Pharma Blood advertising to be published in the April 1 and April 8, 2004 weekly issues of said publication.

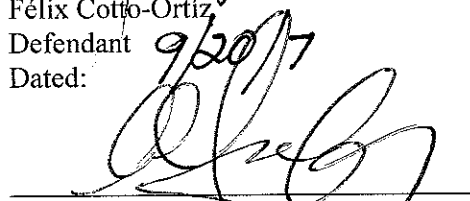
After the execution of said search warrant on December 2, 2003, and continuing through to June 24, 2004, defendant [1] FELIX COTTO-ORTIZ and other persons associated to Pharma Blood continued to operate Pharma Blood Cancer Center in San Juan Bautista Hospital.

Full discovery has been provided to defense.



José A. Ruiz-Santiago
Assistant U.S. Attorney
Chief, Criminal Division
Dated: 9/20/07



Félix Cotto-Ortiz
Defendant
Dated: 9/20/07


Armando González, Esq.
Counsel for Defendant
Dated: 9/20/2007